REMARKS

I. Status of Claims

Upon entry of the Amendment, claims 1-5, 7, and 9-25 are all the claims pending in the application. Claims 22-25 are new. Claims 1-2, 5, 7, 9-10, 15-16, and 18-19 have been amended. Claims 3-4, 11-14, and 17, 20-21 have been canceled.

The Office Action Summary indicates that claims 3, 4, 11-14, and 19-21 have been withdrawn from consideration. Based on the Restriction Requirement dated May 10, 2006, claim 19 should not be withdrawn from consideration. Claim 19 was included in the group that Applicants elected in the Response dated June 8, 2006. Claims 3-4, 11-14, and 20-21 have accordingly been canceled.

Applicants set out the status of the claims 1, 2, 5, 7, 9-10, and 15-18 as understood by Applicants, as the Office Action Summary does not indicate the status of these claims. Claims 1, 2, 5, 7, 9-10, and 15-17 have been rejected. Claim 18 is allowed.

II. Foreign Priority Document

The Examiner is respectfully requested to acknowledge receipt of the priority document.

III. Claim Rejections - 35 U.S.C. § 112

(A) Claims 9 and 10 have been rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the enablement requirement.

Specifically, the Examiner contends that the protein produced by the method of claims 9 and 10 has no enabled use, because a person skilled in the art would allegedly not accept the

applicant's assertion that the protein of SEQ ID NO:1 is expressed in cancer cells or involved in oncogenesis *in vivo*.

For the following reasons, Applicants respectfully traverse this rejection.

The specification provides evidence that the expression of hWAPL protein is involved in the development of cervical cancer that is induced by HPV infection. Example 7 of the specification shows that the hWAPL protein induces chromosome instability, and Example 8 of the specification shows that a cell expressing the hWAPL protein can induce cancer. As such, the hWAPL protein is a target protein for drug development, such as for designing an inhibitor targeted to the hWAPL protein. Such drug development for designing an inhibitor requires the recombinant hWAPL protein having equivalent biological activity to that of natural hWAPL protein.

In addition, such drug development for designing a further siRNA targeted to mRNA of HWAPL requires recombinant mRNA or hWAPL, which is a transcript from the polynucleotide encoding hWAPL protein in a host cell. Such a host cell containing a recombinant expression vector is a useful tool for screening siRNA targeted to mRNA of hWAPL in drug development.

Furthermore, antibodies specific to hWAPL protein are tools for diagnosing the state of development of cervical cancer of human, in which hWAPL is involved. In this regard, the recombinant hWAPL protein is enabling for the generation of antibodies.

(B) Claims 1, 5, and 7 have been rejected under 35 U.S.C. § 112, first paragraph, allegedly because the specification, while being enabling for a polynucleotide comprising the nucleotide

sequence of SEQ ID NO:2, is allegedly not enabling for other polynucleotides encoding the polypeptide of SEQ ID NO:1.

Specifically, the Examiner contends that the specification only establishes that a polynucleotide of SEQ ID NO:2 is overexpressed in cancer cells. Further, since the Examiner concludes that the encoded polypeptide has no enabled use (see above), in the Examiner's opinion, other polynucleotides encoding the polypeptide of SEQ ID NO:1 are likewise not enabled.

For the reasons set forth in response to the rejection of claims 9 and 10 above, this rejection is traversed. Specifically, since the polypeptide of SEQ ID NO:1 is enabled by the present specification, the present specification also enables any polynucleotide encoding the same.

(C) Claim 10 has been rejected is under 35 U.S.C. § 112, first paragraph, as allegedly lacking an adequate written description.

Specifically, the Examiner appears to object to the language "***an*** amino acid sequence of SEQ ID NO:1," because the Examiner interprets this language to include any partial sequence of SEQ ID NO:1.

The amended claims and new claims presented herewith have been amended or drafted to address this issue.

Reconsideration and withdrawal of the Section 112, first paragraph, rejections are respectfully requested.

IV. Claim Rejections - 35 U.S.C. § 102

Claims 1, 2, 5, 7 and 15-17 have been rejected under 35 U.S.C. § 102(b) as being anticipated by Nagase *et al.*, *DNA Research* 3:321-329 (1996) ("Nagase"), as evidenced by Genbank Accession No. D87450.

Specifically, the Examiner contends that Nagase discloses the isolation and sequencing of a cDNA clone (KIAA0261) from a human myeloid cell line, and as evidenced by Genbank Accession No. D87450, this cDNA comprises a nucleotide sequence that is 100% identical to SEQ ID NO:2.

Claim 1 presently recites a polynucleotide encoding hWAPL protein consisting of the amino acid sequence of SEQ. ID. No.1.

In contrast, Nagase as evidenced by D87450, discloses a cDNA clone (KIAA0261) with a reported coding sequence of 3,864 bp, and a deduced amino acid sequence of 1287 amino acids. Nagase and D87450 do not disclose the actual initiating AUG codon.

As shown in the specification, the polypeptide of SEQ ID No. 1 is 1190 amino acids in length, while the putative polypeptide of Nagase is 1287 amino acids in length. Further, the additional ATG included in the 5'-UTR, which is place in frame, could interfere with the translation for recombinant protein of SEQ ID No. 1. Thus, Nagase does not describe or suggest a nucleotide sequence encoding hWAPL protein represented by SEQ ID NO: 1.

Claim 2 depends from claim 1. In this regard, claim 2 is not anticipated for at least the same reasons as claim 1.

Claim 5 is drawn to a recombinant expression vector encoding a polypeptide of SEQ. ID. No.1, wherein the polynucleotide is represented by SEQ. ID. No.2.

As described above, Nagase and D87450 do not disclose the actual initiating AUG codon. The polypeptide encoded by the claimed polynucleotide (i.e., SEQ. ID. No.1) is 1190 amino acids in length, while the putative polypeptide of Nagase is 1287 amino acids in length. The additional ATG included in the 5'-UTR, which is place in frame, could interfere with the translation for recombinant protein of SEQ ID No. 1.

Claim 7 depends from claim 5. Therefore, claim 7 is not anticipated for at least the same reasons as claim 5.

Claim 15 recites a probe consisting of a nucleotide sequence that is complementary to a region of nucleotides 2511 to 2813 of SEQ. ID. No. 2. Nagase and D87450 does not describe or suggest a polynucleotide probe "consisting of" such a nucleotide sequence.

Claim 16 depends from claim 15. Therefore, claim 16 is not anticipated for at least the same reasons as claim 15.

Claims 22 and 23 recite that the polynucleotide of SEQ. ID. No.2 is used as a coding sequence to be translated into the polypeptide of SEQ. ID. No.1.

As described above, Nagase and D87450 do not disclose the actual initiating AUG codon. The polypeptide encoded by SEQ ID. No.1 (i.e., SEQ. ID. No.1) is 1190 amino acids in length, while the putative polypeptide of Nagase is 1287 amino acids in length. The additional ATG included in the 5'-UTR, which is place in frame, could interfere with the translation for recombinant protein of SEQ ID No. 1. In this regard, Nagase fails to describe or suggest a polynucleotide of SEQ ID No. 2, which is used as a coding sequence to be translated into the polypeptide of SEQ. ID. No.1.

Claims 24 and 25 recites that a polynucleotide encoding the polypeptide of SEQ ID NO. 1 is operably linked to a promoter so as to allow expression of said polypeptide.

Nagase does not teach an expression vector as claimed. That is, Nagase does not disclose the claimed polynucleotide operably linked to a promoter so as to produce the polypeptide of SEQ ID NO:1 (which begins at Met^{98} of the putative protein of Nagase).

Further, new claim 24 is patentable over Nagase, because simply inserting the cDNA of Nagase into an expression vector will not necessarily allow for the generation of the polypeptide of SEQ ID NO:1, given the large 5'-UTR unrecognized by Nagase. The Examiner's attention is directed to page 192 of Makrides (cited in the Office Action as "Savvas"), which addresses the impact of a 5'-UTR for recombinant protein production.

Claim 25 depends from claim 24. Therefore, claim 25 is not anticipated for at least the same reasons as claim 24.

V. Claim Rejections - 35 U.S.C. § 103

(A) Claims 16 and 17 have been rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Nagase *et al.*, as evidenced by Genbank Access No. D87450.

Specifically, the Examiner acknowledges that Nagase et al. do not teach a kit.

However, the Examiner contends that it would have been obvious to make a kit useful for the detection of KIAA0261 gene expression, because Nagase teaches that KIAA0261 is an expressed human RNA that encodes a protein.

The Examiner also contends that hybridization probes typically comprise at least 15 bases and are well known in the art.

Applicants respectfully submit that amended claim 15, from which claim 16 depends, recites a probe consisting of a nucleotide sequence that is complementary to a region of nucleotides 2511 to 2813 of SEQ. ID. No. 2. The prior art does not suggest a polynucleotide probe that hybridizes to this region, and as such, neither claim 15 nor claim 16 is *prima facie* obvious.

(B) Claims 9 and 10 have been rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Nagase *et al.*, as evidenced by Genbank Accession No. D87450, and further in view of Savvas, *Protein Expression and Purification* 17:183202 (1999).

Specifically, the Examiner acknowledges that Nagase does not teach a process for producing a recombinant protein in cultured cells. However, the Examiner contends that Savvas teaches the same, and that it would have been obvious to produce the protein encoded by KIAA0261 using the methods described by Savvas.

For the following reasons, Applicants respectfully traverse this rejection.

Savass discloses a recombinant expression system for protein in a mammalian cell. Savass teaches that if no information about the biological activity of the protein of interest is available, there is a wide variety of systems from which to select a suitable expression system for production for the recombinant protein.

Nagase fails to provide the motivation to select a suitable expression system. Nagase fails to provide any specific information about the biological activity of the protein to be expressed from the gene KIAA0261.

Further, Nagase and D87450 do not disclose the actual initiating AUG codon. As such, Nagase fails to suggest the actual initiating AUG codon. Without the actual initiating AUG codon, a person of ordinary skill in the art would not have the motivation to select the correct expression system for producing the claimed recombinant protein.

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,

Ken Sakurabayashi
Registration No. 58,490

SUGHRUE MION, PLLC
Telephone: (202) 293-7060
Facsimile: (202) 293-7860

WASHINGTON OFFICE
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CUSTOMER NUMBER

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